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Biopharmaceutical Company, Cephalon, to Pay $425 Million& Enter Plea to Resolve Allegations of Off-Label Marketing

WASHINGTON – Cephalon Inc. will enter a criminal plea and pay $425 million to resolve claims that it marketed three drugs for uses not approved by the Food and Drug Administration (FDA), the Justice Department announced today.

The lawsuits were brought by former Cephalon employees and filed under the *qui tam* provisions of the False Claims Act. The suits alleged that Cephalon engaged in a scheme to market Gabitril, Actiq and Provigil for unapproved uses in violation of the Food, Drug and Cosmetic Act, which requires a company to specify the intended uses of a product in its new drug application to the FDA. Once approved, the drug may not be marketed or promoted for so-called "off label" uses - any use not specified in an application and approved by FDA.

The suits against the company alleged that, as a result of Cephalon's off-label marketing campaign, false claims for payment were submitted to federal insurance programs such as Medicaid and the Federal Employee Health Benefits Program which did not provide coverage for such off-label uses. A criminal information also filed by the Justice Department alleges that, between approximately January 2001 and 2006, Cephalon also promoted the drugs for uses other than what the FDA approved. The company is charged with one count of Distribution of Misbranded Drugs: Inadequate Directions for Use, a misdemeanor offense.

The FDA approved Actiq for use only in opioid-tolerant cancer patients. Between 2001 and 2006, Cephalon allegedly promoted the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use with patients who were not opioid tolerant.

Gabitril was approved by the FDA for use as an anti-epilepsy drug in the treatment of partial seizures. From 2001 to 2005, Cephalon allegedly promoted the drug as a remedy for anxiety, insomnia and pain. In 2005, following reports of seizures in patients taking Gabitril who did not have epilepsy, the FDA required Cephalon to send a warning letter to doctors advising of the connection between off-label Gabitril use and seizures. The company then ceased promotion of the drug.

Provigil was first approved to treat excessive daytime sleepiness associated with narcolepsy, then expanded the label to include treatment of excessive sleepiness associated with sleep apnea and shift work sleep disorder. From 2001 through 2006, Cephalon allegedly promoted Provigil as a non-stimulant drug for the treatment of sleepiness, tiredness, decreased activity, lack of energy and fatigue. In 2002, the FDA sent Cephalon a letter warning the company not to continue to promote Provigil off-label.

Cephalon undertook its off-label promotional practices via a variety of techniques, such as training its sales force to disregard restrictions of the FDA-approved label, and to promote the drugs for off-label uses.

For example, the Actiq label stated that the drug was for "opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids." Using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other

than oncologists, including general practitioners, and to promote this drug for many uses other than breakthrough cancer pain.

In the case of Gabitril, which had been approved for use for epilepsy, Cephalon told the sales force to visit not just neurologists, but also psychiatrists, and to promote the drug for anxiety and other psychiatric indications. Cephalon also structured its sales quota and bonuses in such a way that sales representatives could only reach their sales goals if they promoted and sold the drugs for off-label uses.

Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of the three drugs. The company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.

In a plea agreement with the United States, Cephalon agreed to pay $50 million to resolve this Information, of which $40 million will be applied to a criminal fine, and $10 million will be applied as substitute assets to satisfy the forfeiture obligation.

In a separate civil settlement executed contemporaneously with this guilty plea agreement, Cephalon will pay $375 million, plus interest, to resolve False Claims Act allegations arising from claims to Medicaid, Medicare and other federal programs, including TRICARE, the Federal Employees Health Benefits program, the Postal Worker's Compensation Program, the Federal Employees Compensation Act Program, the Every Employees Occupational Illness Compensation Program, Department of Veterans Affairs, Defense Logistics Agency, Bureau of Prisons and the Public Health Service Entities. The state Medicaid programs of California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, Texas, Tennessee, Virginia and the District of Columbia will share $116 million of the civil settlement.

"This settlement is further evidence of the Department's willingness to prosecute cases involving violations of the FDCA and to recover taxpayer dollars used to pay for drugs sold as a result of illegal marketing campaigns," said Gregory G. Katsas, Assistant Attorney General for the Justice Department's Civil Division. "The Department takes off-label marketing of drugs very seriously because of the potential for patient harm arising from promoting drugs for uses not approved by the FDA."

The civil settlement resolves four qui tam actions filed in the Eastern District of Pennsylvania. Three of those cases were filed by former Cephalon sales representatives. Relator Paccione will receive $46,469,978 from the federal share of the settlement amount, and those proceeds will be shared by plaintiffs under a separate agreement.

"These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients," said Laurie Magid, acting U.S. Attorney for the Eastern District of Pennsylvania. "This company subverted the very process put in place to protect the public from harm**,** and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgement. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."

As part of the resolution of these allegations, the HHS Inspector General and Cephalon have entered into a five year Corporate Integrity Agreement, which requires Cephalon to send doctors a letter advising of this resolution, that it post payments to doctors on its web site and that its board and top management regularly certify that the company is in compliance with all applicable requirements.

"OIG's compliance agreement with Cephalon will enhance accountability for compliance and improve transparency for patients and physicians," said Department of Health and Human Services Inspector General Daniel R. Levinson. "The agreement requires the company to provide physicians a means to report questionable conduct of sales representatives, requires that payments to physicians be publicly disclosed, and holds the company's board of directors and managers responsible for living up to the compliance agreement."

The case was investigated by the U.S. Attorney's Office in Philadelphia, the Justice Department's Civil Division, the FDA's Office of Criminal Investigation, the Department of Health and Human Services' Office of the Inspector General, the Postal Service Office of the Inspector General, and the Office of Personnel Management Office of Inspector General.

Assistance was provided by representatives of the National Association of Medicaid Fraud Control Units and the Connecticut Attorney General's Office.

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